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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/981,313	10/15/2001	Kristina Marie Burow	36-001100US	4969

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EXAMINER	
SODERQUIST, ARLEN	
ART UNIT	**PAPER NUMBER**
1743	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/05/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/981,313	BUROW ET AL.	
	Examiner	Art Unit	
	Arlen Soderquist	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 November 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19 and 21-74* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19 and 21-74* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on *15 October 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on February 14, 2006 has been entered.

2. Claims 1-19 and 21-74 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 1 "the member rotational robots" and "each member transfer station" do not have antecedent basis. It is noted this terminology appears elsewhere in the claims (at least claims 2-3 and 9).

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 1-719 and 21-74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hutchins (US 5,928,952 or EP 915,341) in view of Brandt (newly cited and applied), Amano (US 4,835,707), Kedar (US 6,323,035), Ishibashi (US 5,087,423) and Stylli (US 5,985,214). Since the patent and publication are part of the same patent family only the patent will be described however equivalent disclosure is found in the publication. In the patent Hutchins teaches a scheduled system and method for processing chemical products. The processing system is for processing a plurality of products, the system including a plurality of

interchangeable units arranged to sequentially receive the products and each having a work station for effecting a specific operation on each of the products, the operation requiring a given time period; and wherein each work station accommodates simultaneously a predetermined number of the products, and the given time period and predetermined number associated with each unit are different than the given time periods and predetermined numbers of other said units. A transport system transports the products through the processing system so as to provide for each product a common occupancy time therein. In discussing prior robotic systems, column 1, lines 22-44 teach that the user of a robotic processing system first arranges processing stations in any convenient pattern and then instructs a robot in given processing actions. Even though programming tasks, once understood by an operator, are not intellectually challenging, the task of setting up a system to operate efficiently is laborious. As the number of stations in a system increased, the number of variables to keep in mind to avoid collisions and otherwise avoid conflicts in instruction made the task laborious even for those skilled in computer programming. In addition, many traditional robotic systems such as those used for drug screening operations utilize a single robotic device with a number of work stations, which perform operations requiring various time periods and may be repeated several times in a complete process. Consequently, the movement of product samples requires complex looping and scheduling for efficient operation which typically is attained by maximizing utilization time of the robotic device. Product throughput of such systems is limited, therefore, by available robotic device time. The object of the Hutchins device and method is to provide a robotic system significantly increasing product throughput of chemical processes such as drug screening. The system has a plurality of rotational robots (23,33,38,43) with at leas one device in the work perimeter. There are several transfer positions/stations (45,62) between the rotational robots. The devices at each rotational robot include storage of assay plates, disposable pipettes and compound plates (26-28), incubator units (12b,12d), washing units (12c), reagent dispensing units (12e) and a reader unit (12g). Column 4, lines 1-4 teach that the transport system is programmed to provide a common occupancy time at each station. Figure 4 and column 4, lines 26-38 describe transfer station 45 which uses pipettes to transfer compounds from a compound plate into an assay plate that is used in the assay. The device is substantially similar to the instant claims except that it

does not teach a pin transfer station or more than one device exclusively within the work perimeter of the rotational robots.

In the paper Brandt teaches multiplexed nanoliter transfers for high throughput drug screening using the Biomek 2000 and the high density replicating tool. They describe a simple pin tool for the Biomek 2000 liquid handling workstation: the High Density Replicating Tool (HDRT) which can have a dramatic effect on the speed and cost drivers of the drug discovery process. The HDRT was originally developed for the Human Genome Project and can perform 96 or 384 simultaneous nanoliter transfers. This tool dramatically reduces waste of mother-daughter plate replication, improves plate process time through multiplexed transfers, and reduces the demands on compounds and reagents by reducing assay volumes by a factor of 10 to 100. The impact of high density, nanoliter volume capability can be far-reaching by not only improving the screening process, but more important, drastically reduce the cost per assay. By reducing the demand on the amounts of compounds needed for screening, the quantities of compounds produced by the combinatorial and parallel chemical synthesis disciplines can be reduced, thereby impacting the speed and costs of the entire drug discovery process.

In the patent Amano teaches an automatic analysis method of and apparatus for the full automation of an enzyme reaction analysis from the pretreatment step of the reaction to the data processing step, wherein the operation of the pretreatment step is arranged to be sequentially performed on many samples with full automation by the use of robots (the robot shown is a rotational robot, 20) and computers to improve savings efficiency and measurement accuracy. Also, the pretreatment steps of weighing samples in many sample tubes, adding the given amount of solvent corresponding to the weighing value and placing the samples into the dissolution vessel to dissolve the sample in the solvent are adapted to be sequentially performed with full automation with the use of the robot, computer and electronic balance. Furthermore, the filtration, concentration and the injecting operations into the HPLC are automatically performed. The automatic apparatuses are coupled to each other so that the filtration, concentration, injecting operations are allowed to be sequentially performed with full automation using an on-line system. The summary of the invention describes several stations for treating the samples and two separate rotation robots to move the samples and treat them. In particular the device includes a weighing and dissolution apparatus, grasping a sample tube retained in a rack

with a chuck provided on a movable arm of a first automatic robot for weighing the sample with an electronic balance, adding a predetermined amount of solvent to the sample in accordance with the weighing value of the sample, placing the sample tube into the dissolution vessel to dissolve the sample after the addition of solvent, moving the sample tube containing the dissolved sample onto a rack for dilution provided on a dilution and reacting apparatus; with the dilution and reacting apparatus, grasping a nozzle of a dilution dispenser, a sampling pipetter or an enzyme reaction mixture dispenser with the chuck of a second automatic robot to move the nozzle into the sample tube retained on the dilution rack or the reaction tube retained on a rack in an incubator, adding the diluted solution from the dilution dispenser into the sample tube located in the dilution rack to perform the diluting operation by a given amount, taking a sampling of the diluted solution from the sample tube with the sampling pipetter to inject it into the reaction tube, sequentially injecting enzymes and factors necessary for the enzyme reaction into the reaction tube at intervals of a given time, grasping the reaction tube with the second robot to move it into the preservation vessel after the reaction; grasping the reaction tube retained in the preservation vessel with the second robot to place it in the position of a reaction mixture sampling needle disposed in a filtration, concentration and analysis apparatus, filtering the reaction mixture through a filtration unit after the sampling operation of reaction mixture with the sampling needle, feeding eluate into a concentration column after adsorption of the filtrate onto the concentration column, automatically injecting it into an analysis column for analysis by a HPLC, processing the obtained data by a data processing apparatus; and automatically controlling the operations of the first and second robots in accordance with a program input into a computer to automatically perform all of the operations from weighing to analysis.

In the patent Kedar teaches systems and methods for handling multi-well plates. In one example a system is provided with a rotational robot having a base member and at least one arm. The arm includes a grasping mechanism which is adapted to grasp the plate. Further, the grasping mechanism is configured to receive the plate in a repeatable and known location such that the location of each well relative to the grasping mechanism is known by the robot. The invention relates generally to the field of device handling and manipulation, and particularly to the handling and manipulation of multi-well plates. In one particular aspect, the invention provides for the transport of multi-well plates to precise and known locations at various

processing or evaluation stations. The use of multi-well plates to facilitate the performance of various chemical and biological procedures has become widely accepted. Such multi-well plates are typically rectangular in geometry and have a two dimensional array of wells (8 by 12 or 96 wells). To accommodate the performance of various procedures, the wells of such plates are configured to receive various chemicals or substances. One common procedure is the performance of assays where various chemicals or substances are introduced into the wells and any reactions are evaluated. One type of assay evaluation may proceed by placing the plate above a camera to detect an emitted signal from the wells. When using multi-well plates, it is often desirable to efficiently deliver and/or remove various chemicals or substances into or from the wells. This often requires the plate to be moved to various pieces of processing equipment for filling or removal. Further, the plates may also need to be transported to evaluation equipment for detection or other evaluation. When introducing or removing fluids or substances into or from the wells, and when evaluating the substances within the wells, the wells typically need to be aligned with distal tips, detection devices and the like. However, since various pieces of equipment may be needed to complete a procedure, each time the plate is moved to a different piece of equipment, the plate will need to be properly oriented according to the specifications of the given piece of equipment. For example, many types of fluid delivery equipment include a stage on which the plate is placed. Often a robot is employed to grasp the plate and move the plate to the stage. However, such robots typically have a pair of grasping fingers that grasp the plate in an arbitrary manner and then place the plate on the stage. Once on the stage and removed from the robot, the dispensing tips will need to be aligned with the wells in the plate. Such a system is often burdensome and time consuming. Moreover, as it becomes more desirable to increase the numbers of wells in the plate while reducing their size, it becomes more difficult to precisely align the wells with various pieces of equipment. For example, many types of filling equipment are provided with 96 dispensing tips. If an 864 well plate is placed on a stage which can move only in the vertical direction, it is difficult, if not impossible, for the 96 dispensing tips to fill all of the 864 wells while the plate remains fixed on the stage. Hence, it would be desirable to provide systems, devices and methods to facilitate the transport of multi-well plates between various pieces of equipment in a manner such that the wells may be efficiently accessed or evaluated. The Kedar apparatus is taught as fulfilling this desire.

In the patent Ishibashi teaches an automatic analyzing device having a plurality of analyzing modules, a plurality of analyzing routes and at least one bypass route bypassing at least one analyzing module. Each analyzing module is capable of analyzing samples with respect to one or more items, and samples successively supplied from the introduction sides of the modules are selectively delivered into each module in accordance with the possible analyzing items of each module and the analyzing items of the samples to be analyzed. The sample cup can pass the module via a bypass or can be returned to the introduction side of the module via a bypass, in accordance with the items to be analyzed, the effective distribution of the sample cups can be performed. Column 1, lines 19-45 discuss known analyzing apparatus in which analyzing modules ranging from two to eight are serially arranged, and sample cups each containing sample liquids to be analyzed are successively conveyed to the modules one by one via only one route. Necessary amounts of the samples are picked up and delivered into reaction vessels in the modules according to the analyzing items of each sample that are to be analyzed by each module. Although it is not necessary to analyze all items for each sample, all samples have to be successively fed to each of the analyzing modules. Since the each module can analyze from four to twelve items, it is possible to analyze 20-30 items in the automatic analyzing apparatus as a whole. Generally, not all samples require the same analyzing items. In general, a sample requires only 50-60% of all possible analyzing items of the apparatus. In other words, 40-50% of the analysis capacity is not being used for each respective sample. Lines 47-57 explain that this is a disadvantage since it increases the processing/analysis time. To solve this problem Ishibashi teaches arranging the analysis modules in a parallel or serial manner and transferring the sample cups to the module that performs the required analysis/analyses without respect to the order in which the sample cups were supplied with sample (see column 2, lines 11-57). In other words the samples are sent directly to the analysis modules that are required by providing a bypass path around analysis modules that are unnecessary. Lines 58-60 teach that this allows the apparatus to operate all of the analyzing modules efficiently without waste of time.

In the patent Stylli teaches systems and methods for rapidly identifying useful chemicals in liquid systems and uses automated and integratable workstations for identifying chemicals having useful activity. The present invention is also directed to chemical entities and information (e.g., chemical or biological activities of chemicals) generated or discovered by

operation of workstations of the present invention. The present invention includes automated workstations that are programmably controlled to minimize processing times at each workstation and that can be integrated to minimize the processing time of the liquid samples from the start to finish of the process. Systems and methods for rapidly identifying chemicals with biological activity in samples, especially small liquid samples, can benefit a number of different fields. For instance, the agrochemical, pharmaceutical, and cosmetic fields all have applications where large numbers of liquid samples containing chemicals are processed. Currently, many such fields use various strategies to reduce processing times, such as simplified chemistry, semi-automation and robotics. While such strategies may improve the processing time for a particular type of liquid sample, process step or chemical reaction, such methods or apparatuses can seldom integrate the entire process, especially the generation or detection of chemical events in small volumes. Such apparatus are also often limited in their application, since many of them are designed for, and dedicated to, a particular type of liquid sample or chemical reaction. In most processes involving liquid samples, as the complexity of the liquid sample processing increases the process time per sample increases. Although, some very simple chemical reactions or liquid processing methods can achieve extremely high throughput rates, such as in the manufacturing of containerized liquids, complicated processing of liquids is typically several orders of magnitude slower. In some instances, the processing of liquid samples, such as in pharmaceutical arts, which usually demands complicated liquid processing for drug discovery, can obtain throughput rates of approximately 3,000 samples per day. This type of processing in general, however, uses liquid sample volumes on the order of 100 to 200 microliters, which often requires relatively large amounts of exotic and expensive reagents, and does not typically incorporate automated access to large stores of liquid reagents. Consequently, there is a need to provide components, systems and methods for rapidly processing liquid samples at high throughput rates, particularly liquid samples of microliter volumes, one to ten microliters, to identify chemicals with useful activity. Columns 2-3 teach several modules for the Stylli apparatus. Columns 3-5 provide several definitions of which adaptive routing, daughter plate and parallel processing are relevant to the ability to increase the through put of the device. Column 18, lines 33-50 teach various rates of throughput going up to 10 million wells processed in a day. The following paragraph explains how parallel processing can be used to increase the throughput.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide several modules as taught by Stylli or Ishibashi and incorporate parallel processing of Stylli or the non sequential sample transport of Ishibashi into the Hutchins apparatus because of the ability increase the throughput as taught by Stylli and to operate each analysis/processing module efficiently and reduce wasted time due to the successive treatment of the samples as taught by Ishibashi. It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize the multi-well plates of Stylli or Kedar along with the plate grasping mechanism of Kedar into the Hutchins device because of the ability to increase throughput or facilitate the efficient processing of samples as taught by Kedar and Stylli. It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize the high density replicating pin tool of Brandt in the Hutchins device because of the impact of high density, nanoliter volumes leading to improving the screening process, drastically reducing the cost per assay, reducing the demand on the amounts of compounds needed for screening and reducing the quantities of compounds produced by the combinatorial and parallel chemical synthesis disciplines, thereby impacting the speed and costs of the entire drug discovery process as taught by Brandt. It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide multiple devices within the work perimeters of the rotational robots as taught by Amano or Kedar in the Hutchins device because of the ability to prepare compounds and the need to use multiple devices to weigh and/or dissolve and/or dilute samples or compounds prior to analysis as taught by Amano or to facilitate the processing of the samples as taught by Kedar.

5. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The additionally cited art teaches automation and pin tools used for various applications.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arlen Soderquist whose telephone number is (571) 272-1265. The examiner can normally be reached on Monday-Thursday and Alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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